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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,623	07/11/2005	Robert Johan Joseph Hageman	0012/73640/NHZ	7309
7590 Cooper & Dunham 1185 Avenue of the America New York, NY 10036			EXAMINER GUDIBANDE, SATYANARAYAN R	
			ART UNIT 1654	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,623	Applicant(s) HAGEMAN ET AL.	
	Examiner SATYANARAYANA R. GUDIBANDE	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 18-33 is/are pending in the application.
- 4a) Of the above claim(s) 26-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 18, 19 and 21-25 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/17/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of group I invention (claims 1, 18-25) and election of caseinates from milk as the preferred species of protein (claim 1); guanidine acetic acid as the preferred species of glycoamine (claim 1); folic acid as the preferred species of vitamin (claim 21); maltodextrin as the preferred species of food grade carbohydrate (claim 22); magnesium as the preferred species of mineral (claim 24); powder as the preferred form of composition (claim 25); and neurological disorders as the preferred form of disorder (claim 33) in the reply filed on 12/27/07 is acknowledged. The traversal is on the ground(s) that the cited reference of Vincent to show that the instant invention lacks unity of invention is drawn to a method of treating acid gastric hypersecretion and protecting the gastric mucosa and liver via a composition of p. chlorhippuric acid or a salt thereof with a mineral or organic base which may or may not contain either serine or glycoamine are entirely unrelated and irrelevant to the claims of the instant application. This is not found persuasive because the Vincent reference is drawn to the pharmaceutical compositions **comprising** of serine and glycoamine (column 2, lines 12 and 13) and reads on the instant invention and hence as stated in the election/restriction dated 10/1/07 that the invention of group I of the instant invention is not a contribution over the prior art of Vincent.

Applicants further argue that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the claims of Groups II-IV would not require a serious burden once the prior art relevant to Group I has been identified. This is not persuasive because, the group IV invention is drawn to the

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method for the prevention and/or treatment of disorders selected from the group consisting of cancer, neurological disorders, migraine, allergy, insulin resistance which improves glucose tolerance and decreases side effects of diabetes type II, cardiovascular and cerebrovascular disorders, hypercholesterolaemia, hypertension, subfertility, uncontrolled inflammation processes, pneumonia, hearing loss, wound healing, gut barrier function and sepsis. The etiology of the disease conditions listed in group IV invention are distinct to each condition and affects different patient population. Search for treatment of one disease does not lead to information on the others. Hence there is a search burden along with the inventions of groups I-IV being distinct from one another.

It is noted that Applicants also stated that “[t]he inventions of Groups I-IV are not independent and are not distinct. Under M.P.E.P § 802.01, ‘independent’ means there is no disclosed relationship between the subject matter claimed. The inventions of Group I-IV are related.” It is unclear as the assertions by Applicant. The MPEP states “Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.” The MPEP states, when discussing independent and distinct “Related inventions are **distinct** if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and **wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the**

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prior art).” See MPEP 802.01 By asserting that “[t]he inventions of Groups I-IV are not independent and are not distinct,” Applicants seem to be implying that the inventions of Group I-IV are not patentable over the other, or put it another way that they are obvious over one another. For clarity of record, Applicants are requested to clarify their assertions of “[t]he inventions of Groups I-IV are not independent and are not distinct.” If Applicants believe that the “inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case.” In this case, the restriction will be withdrawn. However, “[i]n either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.”

Therefore, the requirement is still deemed proper and is therefore made FINAL.

Claims 1 and 18-33 are pending.

Claims 26-33 have been withdrawn from further consideration as being drawn to non-elected invention.

Claims 1, 18-25 are examined on the merit.

Claim Objections

Claim 20 is objected to because of the following informalities: claim 20 depends on claim 3 which has been canceled. Appropriate correction is required.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 18, 19 and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,148,912 issued to Vincent in light of the information available from website <http://www.scientificpsychic.com/fitness/carbohydrates.html>.

In the instant application, applicants claim a nutritional or pharmaceutical composition comprising of L-serine and glycoamine and the composition is free of glycine.

Vincent discloses a pharmaceutical composition that comprises of serine (also salts of casein) and glycoamine (column 2, lines 12 and 13). The composition in the cited reference is devoid of glycine and therefore, the limitation that the weight ratio of L-serine to glycine after hydrolysis of the composition is more than 2.7:1 is moot. Hence meets the limitation of 1 and 18. The composition of cited reference also comprises of creatinine (column 2, line 13) and hence reads on claim 19. The cited reference also discloses amino sugars such as glucosamine, that represents the food grade amino acid. (column 2, line 16) that reads on the instant claim 22. The reference of Vincent also teaches potato starch (column 5, example 8, line 40), a source of maltodextrin. Since the sugar glucosamine is an aldehyde sugar (see information available on website: '<http://www.scientificpsychic.com/fitness/carbohydrates.html>'), it meets the limitation of claim 23. The website reference is post dated to the effective filing date of the instant

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application. "In certain circumstances, references cited to show a universal fact need not be available as prior art before applicant's filing date. In re Wilson, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism." See MPEP 2124.

The reference also teaches the presence of minerals such as magnesium (column 1, line 68) and reads on the instant claim 24. Vincent also teaches that the composition is in the form of powders (column 1, line 62) and hence meets the limitation of claim 25.

Therefore, the cited reference of Vincent anticipates the claims 1, 18, 19 and 22-25 of the instant invention.

Claims 1, 18, 19 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,582,807 issued to Veeraraghavan in light of the information available from website <http://www.scientificpsychic.com/fitness/carbohydrates.html>.

In the instant application, applicants claim a nutritional or pharmaceutical composition comprising of L-serine and glycocyamine and the composition is free of glycine.

Veeraraghavan discloses a composition for a medium (a nutritional broth for mycobacteria) for the cultivation of mycobacteria that comprises of serine (column 11, line 10), glycocyamine (column 11, lines 16 and 17). The composition is devoid of glycine and hence meets the limitation of 1 and 18 (claim 1 of the cited reference). The composition of cited reference also comprises of creatinine (column 11, line 15) and hence reads on claim 19. The cited reference also discloses amino sugars such as glucosamine, arabinose, galactose, mannose, d-ribose and mixtures thereof (column 11,

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lines 21-23) that reads on the instant claim 22. Since the sugar glucosamine and mannose, etc., are an aldehyde sugars (see information available on website:

'<http://www.scientificpsychic.com/fitness/carbohydrates.html>'), it meets the limitation of claim 23. The website reference is post dated to the effective filing date of the instant application. "In certain circumstances, references cited to show a universal fact need not be available as prior art before applicant's filing date. In re Wilson, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism." See MPEP 2124. The reference of Veeraraghavan also teaches the presence of minerals such as magnesium (column 4, line 41) and reads on the instant claim 24. Veeraraghavan also teaches the vitamins in the composition specifically folic acid (column 4, line 28) and hence meets the limitation of claim 21.

Therefore, the cited reference of Vincent anticipates the claims 1, 18, 19 and 21-24 of the instant invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recite a limitation 'the weight ratio of L-serine to glycine after hydrolysis of the composition is more than 2.7:1'. The claim as recited is unclear because, whether the composition comprises of hydrolysate wherein the ratio of serine to glycine is more

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than 2.7:1 or the ratio of serine to glycine is more than 2.7:1 after ingestion of the composition and the composition undergoes hydrolysis.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites a limitation, "wherein the molar ratio of the energy metabolism precursor and the excess of L-serine versus glycine is in the range of 0.01: 1 to 10:1". From the claim is recited it is unclear as what this range of ratio 0.01: 1 to 10:1 refers to? Whether it refers to the ratio of energy metabolism precursor to serine, or energy metabolism precursor to glycine. It is unclear, the meaning of the term, 'serine versus glycine'. It is unclear whether the ratio represents the ratio of energy metabolism precursor against the ratio of serine to glycine, i.e., energy metabolism precursor : serine/glycine.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

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There are several cited references in the specification. The references should be submitted in the form IDS along with legible copies of non-patent and foreign patent literature for consideration.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654